Amendments to the Specification

Please replace the paragraph beginning on page 19, line 13, with the following amended paragraph:

The most distal electrode on the composite subcutaneous electrode is a coil electrode 27 that is used for delivering the high voltage cardioversion/ defibrillation energy across the heart. The coil cardioversion/defibrillation electrode is about 5-10 cm in length. Proximal to the coil electrode are two sense electrodes, a first sense electrode 25 is located proximally to the coil electrode and a second sense electrode 23 is located proximally to the first sense electrode. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 29. Similar types of cardioversion/defibrillation electrodes are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022, the entire disclosure of which is herein incorporated by reference, ~~disclosures~~ discloses a composite electrode with a coil cardioversion/defibrillation electrode and sense electrodes. Modifications to this arrangement [[is]] are contemplated within the scope of the invention. One such modification is illustrated in FIG. 2 where the two sensing electrodes 25 and 23 are non-circumferential sensing electrodes and one is located at the distal end, the other is located proximal thereto with the coil electrode located in between the two sensing electrodes. In this embodiment the sense electrodes are spaced about 6 to about 12 cm apart depending on the length of the coil electrode used. FIG. 3 illustrates yet a further embodiment where the two sensing electrodes are located at the distal end to the composite electrode with the coil electrode located proximally thereto. Other possibilities exist and are contemplated within the present invention. For example, having

only one sensing electrode, either proximal or distal to the coil cardioversion/ defibrillation electrode with the coil serving as both a sensing electrode and a cardioversion/defibrillation electrode.

Please replace the paragraph beginning at page 26, line 1, with the following amended paragraph:

FIG. 7 schematically illustrates the method for implanting the S-ICD of the present invention. An incision 31 is made in the left anterior axillary line approximately at the level of the cardiac apex. This incision location is distinct from that chosen for S-ICD placement and is selected specifically to allow both canister location more medially in the left inframammary crease and lead positioning more posteriorly via the introducer set (described below) around to the left posterior axillary line lateral to the left scapula. That said, the incision can be anywhere on the thorax deemed reasonably by the implanting physician although in the preferred embodiment, the S-ICD of the present invention will be applied in this region. A subcutaneous pathway 33 is then created medially to the ~~inframmary~~ inframammary crease for the canister and posteriorly to the left posterior axillary line lateral to the left scapula for the lead.

Please replace the paragraph beginning at page 26, line 17, with the following amended paragraph:

The S-ICD canister 11 is then placed subcutaneously at the location of the incision or medially at the subcutaneous region at the left ~~inframmary~~ inframammary crease. The subcutaneous electrode 13 is placed with a specially designed curved introducer set 40 (see FIG. 8). The introducer set comprises a curved trocar 42 and a stiff curved peel away sheath 44. The peel away sheath is curved to allow for placement around the rib cage of the patient in the subcutaneous space created by the trocar. The sheath has to be stiff enough to allow for the placement of the electrodes without the sheath collapsing or bending. Preferably the sheath is made out of a biocompatible plastic material

and is perforated along its axial length to allow for it to split apart into two sections. The trocar has a proximal handle 41 and a curved shaft 43. The distal end 45 of the trocar is tapered to allow for dissection of a subcutaneous path 33 in the patient. Preferably, the trocar is cannulated having a central Lumen 46 and terminating in an opening 48 at the distal end. Local anesthetic such as lidocaine can be delivered, if necessary, through the lumen or through a curved and elongated needle designed to anesthetize the path to be used for trocar insertion should general anesthesia not be employed. The curved peel away sheath 44 has a proximal pull tab 49 for breaking the sheath into two halves along its axial shaft 47. The sheath is placed over a guidewire inserted through the trocar after the subcutaneous path has been created. The subcutaneous pathway is then developed until it terminates subcutaneously at a location that, if a straight line were drawn from the canister location to the path termination point the line would intersect a substantial portion of the left ventricular mass of the patient. The guidewire is then removed leaving the peel away sheath. The subcutaneous lead system is then inserted through the sheath until it is in the proper location. Once the subcutaneous lead system is in the proper location, the sheath is split in half using the pull tab 49 and removed. If more than one subcutaneous electrode is being used, a new curved peel away sheath can be used for each subcutaneous electrode.

Please replace the paragraph beginning at page 28, line 9, with the following amended paragraph:

The S-ICD will have prophylactic use in adults where chronic transvenous/epicardial ICD lead systems pose excessive risk or have already resulted in difficulty, such as sepsis or lead fractures. It is also contemplated that a major use of the S-ICD system of the present invention will be for prophylactic use in children who are at risk for having fatal arrhythmias, where chronic transvenous lead systems pose significant management problems. Additionally, with the use of standard transvenous ICDs in children, problems develop during

patient growth in that the lead system does not accommodate the growth. FIG. 9 illustrates the placement of the S-ICD subcutaneous lead system such that he problem that growth presents to the lead system is overcome. The distal end of the subcutaneous electrode is placed in the same location as described above providing a good location for the coil cardioversion/defibrillation electrode 27 and the sensing electrodes 23 and 25. The insulated lead 21, however is no longer placed ~~in a taught~~ in a taut configuration. Instead, the lead is serpiginously placed with a specially designed introducer trocar and sheath such that it has numerous waves or bends. As the child grows, the waves or bends will straighten out lengthening the lead system while maintaining proper electrode placement. Although it is expected that fibrous scarring especially around the defibrillation coil will help anchor it into position to maintain its posterior position during growth, a lead system with a distal tine or screw electrode anchoring system 52 can also be incorporated into the distal tip of the lead to facilitate lead stability (see FIG. 1). Other anchoring systems can also be used such as hooks, sutures, or the like.

Please replace the paragraph beginning at page 35, line 12, with the following amended paragraph:

The two cardioversion/defibrillation electrodes on the housing are used for delivering the high voltage cardioversion/defibrillation energy across the heart. In the preferred embodiment, the cardioversion/defibrillation electrodes are coil electrodes, however, other cardioversion/defibrillation electrodes could be used such as having electrically isolated active surfaces or platinum alloy electrodes. The coil cardioversion/defibrillation electrodes are about 5-10 cm in length. Located on the housing between the two cardioversion/defibrillation electrodes are two sense electrodes 1425 and 1427. The sense electrodes are spaced far enough apart to be able to have good QRS detection. This spacing can range from 1 to 10 cm with 4 cm being presently preferred. The electrodes may or may not

be circumferential with the preferred embodiment. Having the electrodes non-circumferential and positioned outward, toward the skin surface, is a means to minimize muscle artifact and enhance QRS signal quality. The sensing electrodes are electrically isolated from the cardioversion/defibrillation electrode via insulating areas 1423. Analogous types of cardioversion/defibrillation electrodes are currently commercially available in a transvenous configuration. For example, U.S. Patent No. 5,534,022, the entire disclosure of which is herein incorporated by reference, discloses a composite electrode with a coil cardioversion/defibrillation electrode and sense electrodes. Modifications to this arrangement [[is]] <u>are</u> contemplated within the scope of the invention. One such modification is to have the sense electrodes at the two ends of the housing and have the cardioversion/defibrillation electrodes located in between the sense electrodes. Another modification is to have three or more sense electrodes spaced throughout the housing and allow for the selection of the two best sensing electrodes. If three or more sensing electrodes are used, then the ability to change which electrodes are used for sensing would be a programmable feature of the US-ICD to adapt to changes in the patient physiology and size over time. The programming could be done via the use of physical switches on the canister, or as presently preferred, via the use of a programming wand or via a wireless connection to program the circuitry within the canister.

Please replace the paragraph beginning at page 40, line 13, with the following amended paragraph:

Figures 19-26 refer generally to alternative S-ICD/US-ICD canister embodiments. Although the following canister designs, various material constructions, dimensions and curvatures, discussed in detail below, may be incorporated into either S-ICD or US-ICD canister ~~embodimens~~ <u>embodiments</u>, hereinafter, these attributes will be discussed solely with respect to S-ICDs.

Please replace the paragraph beginning on page 60, line 5, with the following amended paragraph:

A "spade" shaped electrode 236 is depicted in Figure 23A. The distal end of the spade shaped electrode also generally follows the outline of the rounded distal end 234 of the canister housing 220. As the spade shaped electrode 236 moves proximally along the length of the canister housing 220, the conductive surface terminates in a rounded proximal end. Similar to the thumbnail embodiment described above, the spade shaped electrode's conductive surface is generally contained within the distal end 234 of the canister housing 220. In alternate embodiments, the spade shape electrode's conductive surface may extend proximally further within the canister housing 220. In yet another spade shaped electrode [[234]] 236 embodiment, the margins of the spade shaped electrode's conductive surface refrain from following the exact rounded contour of the canister housing 220, but substantially form a spade shaped configuration.

Please replace the paragraph beginning at page 75, line 15, with the following amended paragraph:

Turning now to Figure 23A, a S-ICD canister 220 having a duckbill-shaped canister housing 222 is shown. The duckbill-shaped canister housing 222 has a proximal end 226 and a distal end 234. The proximal end 226 of the duckbill-shaped canister housing 222 further includes a main housing member 228 and a distal housing member 230. The distal housing member 230 is an elongated segment extending distally from the distal end of the main housing member 228. Although the two segments differ in their size and shape, the distal housing member 230 and main housing member 228 are generally contiguously and fluidly attached to one another and may be formed from a single mold. In alternative embodiments, however, the distal housing member 230 may be hinged to the main housing member 228. The distal housing member 230 also generally comprises a material that is similar in composition to that forming the main housing member 228. In alternate embodiments, however, the distal housing

member 230 may include a material that ~~possess~~ possesses enhanced electrically insulated characteristics.

Please replace the paragraphs beginning on page 78, line 12, and ending on page 79, line 9, with the following amended paragraphs:

Extending distally beyond the shoulder region 232 is the distal head [[234]] 224 of the distal housing member 230. The distal head [[234]] 224 is the distal termination point of the duckbill-shaped S-ICD canister 220. The distal head [[234]] 224 includes a generally rounded end. In one embodiment, illustrated in Figure 23B, the distal head [[234]] 224 has a width greater than the width at a location within the shoulder region 232 of the distal housing member 230. In alternative embodiments, the distal head's width is equal to or less than the width at any point in the shoulder region 232 of the distal housing member 230, as illustrated in 23A.

The length of the duckbill-shaped S-ICD canister 220 may depend highly upon the shape and size of the distal housing member 230. In particular embodiments, the duckbill-shaped S-ICD canister 220 is approximately 30 centimeters long or less. In alternative embodiments, the duckbill-shaped S-ICD canister 220 is approximately 10 centimeter or less. In particular embodiments, the length of the duckbill-shaped S-ICD canister 220 may be curved, or alternatively, or a portion of the length (i.e., the shoulder region 232 and distal head [[234]] 224) are curved.

Please replace the paragraphs beginning on page 80, line 11, and ending on page 81, line 10, with the following amended paragraphs:

In certain embodiments of the present invention, the electronic components (e.g., circuitry, batteries and capacitors) of the S-ICD canister 220, are generally absent from the distal housing member 230. As such, the depth of the distal housing member 230 may be greatly reduced. In these embodiments, a

depth of approximately 1 millimeter may be obtained at the distal head [[234]] 224 of the duckbill-shaped S-ICD canister 220.

The duckbill-shaped distal housing member 230 enhances navigation during canister implantation. The distal head [[234]] 224 of the distal housing member 230 is blunt at its end to reduce trauma suffered to surrounding tissue during the S-ICD canister's advancement or during chronic implantation. Similarly, the narrower distal head [[234]] 224 (width-wise and depth-wise) is easier to control during the advancement procedure. The smaller distal head [[234]] 224 also enables a physician to navigate the smaller and more compact tissues adjacent to the sternum, which a larger head might otherwise find unobtainable. Moreover, the narrower distal head [[234]] 224 may be advanced to a location in close proximity to the patient recipient's heart 218 without concern of distorting or stressing the skin in the left parasternal region.